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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,154	08/18/2003	Jeffrey E. Stahmann	GUID.103PA	3600

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EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,154	STAHMANN ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48 and 80-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48 and 80-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-48 and 80-100 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-48 and 80-100 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-97 of copending Application No. 10/643,203 (US Patent Publication 20050039745 A1). Although the conflicting claims are not identical, they are not patentably distinct from

each other because both applications claim the used of providing detecting and treating disordered breathing through delivery of cardiac electrical therapy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-48 and 80-100 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 and 33-96 of copending Application No. 10/642,998 (US Patent Publication 20050042589 A1) in view of Park et al. (US 6,928,324). Application No. 10/642,998 claims the Applicant's invention except for the delivery of cardiac electrical treatment. Park et al. claims to employ one or more pulse generators that are capable of generating cardiac pacing pulses, wherein the circuitry is responsive to the detected sleep apnea condition to control the one or more pulse generators to generate cardiac pulses with a timing that tends to terminate the detected sleep apnea condition, as set forth in claim 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detection device as taught by Application No. 10/642,998 to include the treatment as taught by Park et al., since such a modification would enable the patient to have treatment delivered upon the detection of an apnea event or precursor, and thus reduce the hiatus between detection and treatment.

This is a provisional obviousness-type double patenting rejection.

3. Claims 1-48 and 80-100 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

102 of copending Application No. 10/643,016 (US Patent Publication 20050043644 A1) in view of Park et al. (US 6,928,324). Application No. 10/643,016 claims the Applicant's invention except for the delivery of cardiac electrical treatment. Park et al. claims to employ one or more pulse generators that are capable of generating cardiac pacing pulses, wherein the circuitry is responsive to the detected sleep apnea condition to control the one or more pulse generators to generate cardiac pulses with a timing that tends to terminate the detected sleep apnea condition, as set forth in claim 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detection device as taught by Application No. 10/643,016 to include the treatment as taught by Park et al., since such a modification would enable the patient to have treatment delivered upon the detection of an apnea event or precursor, and thus reduce the hiatus between detection and treatment.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-9, 14-18, 20, 22-27, 30-34, 37, 39-45, 47-48, 80-83, 85-86, 88-96, 98 and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourgeois et al. (US 6,126,611). Bourgeois et al. discloses an apparatus for treating sleep apnea, by

detecting one or more conditions and predicting disordered breathing and delivering stimulation. Bourgeois et al. discloses in col. 3, lines 51-54, "the device is arranged to sense an apnea event. In one embodiment a decrease in heart rate below a given threshold is taken as an indication of the onset of sleep apnea." Since Bourgeois et al. detects an indication of the onset of sleep apnea, Bourgeois et al. predicts disordered breathing. Furthermore, Bourgeois et al. discloses "once triggered by detection of low cardiac rate, minute ventilation or respiratory rate, the pacing system of the present invention would begin to pace rapidly, e.g. 90 bpm"(col. 3, lines 36-37) in order to provide therapy.

As to claims 18, 20 and 23, Bourgeois et al. discloses the prediction and subsequent treatment of disordered breathing. Therefore, Bourgeois et al. discloses the "disordered breathing will occur within a selected time interval from a time of the disordered breathing prediction". Additionally, since this prediction occurs during rest, the time interval occurs during the next "sleep time".

As to claims, 41-45, "pacemaker 10 is capable of operating in various non-rate-responsive modes which include DDD, DDI, VVI, VOO, AOO, VDD. DVI, AAT and VVT, as well as corresponding rate-responsive modes of DDDR, DDIR, VVIR, VOOR and VVTR".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 19-21, 43-44, 46, 84 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois et al. (US 6,126,611). Bourgeois et al. disclose the claimed invention except for the time interval. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the time interval, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

As to claim 84, although Bourgeois et al. does discloses the employment of a respiratory sensor in conjunction with the pacing system, Bourgeois et al. does not disclose an external sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the internal sensor as taught by the Bourgeois et al. with the external sensor as taught by Terry, Jr. et al., since such a modification is less invasive and can be worn or used by the sleep apnea patient only at times when the intention or expectation is to sleep.

As to claims 43-44, 46 and 99, Bourgeois et al. discloses the claimed invention except for the non-excitatory pacing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pacing therapy

as taught by Bourgeois et al. with the non-excitatory pacing, since such a modification would modify the pacing therapy to meet specific patients needs.

2. Claims 10-13 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois et al. (US 6,126,611) in view of Bardy (US 6,398,728 B1). Bourgeois et al. discloses the claimed invention except for the non-physiological and medical history. Bardy teaches that it is known to input medical history and monitor environmental factors as set forth in column 1, lines 33-43, since both factors affect respiratory disease. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detected data as taught by Bourgeois et al. with the detected data as taught by Bardy, in order to modify treatment to meet specific patient needs.

3. Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois et al. (US 6,126,611) in view of Terry, Jr. et al. (US 5,335,657). Bourgeois et al. disclose the claimed invention except for the operation to conserve the life of the IMD. Terry, Jr. et al. teaches that it is known to utilize batteries for reliable long-lasting use in implantable devices as set forth in column 7-8, lines 58-64 and 44-48 respectively, for the purpose of conserve energy in an implantable device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the operation of the IMD as taught by Bourgeois et al. with the operation to conserve the life of the IMD as taught by Terry, Jr. et al., since such a modification would enable the life of the IMD to be prolonged and thus reduce the need

for explanation or maintenance. Furthermore, long-lasting batteries are conventionally used in powering implantable medical electronic devices.

4. Claims 35-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois et al. (US 6,126,611) in view of DiLorenzo (US Patent US 6,366,813 B1). Bourgeois et al. disclose the claimed invention except for the estimated probability, accuracy or sensitivity. DiLorenzo teaches that it is known to estimate, or model, of fluctuation may be based upon a combination of preset, learned, and real-time sensed parameters as set forth in column 42, lines 50-60, for the purpose of prediction of future symptomatology, cognitive and neuromotor functionality, and treatment magnitude requirements. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the predictive criteria as taught by the modified Testerman et al. with the adjusted or modified predictive criteria as taught by DiLorenzo, in order to determine relevant data, prevent outliers and create accurate predictions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alyssa M Alter
Examiner
Art Unit 3762

GEORGE R. EVANISKO
PRIMARY EXAMINER
5/29/7